viewpoint, they risk the harms of increasing the distress of vulnerable parents and, by selection influences, obtaining results which may not be generalisable. The burden of research may be borne disproportionately by more vulnerable and deprived families. A system of presumed consent, with opting out, for including sick neonates in appropriate trials would overcome some of these ethical problems. It would respect autonomy in acknowledging the difficulties of obtaining informed consent in emergency neonatal research. It might reduce selection bias, thus producing more generalisable conclusions, and might be more equitable. Experience with opting out in non-urgent research, and in organ donation, suggests that recruitment might increase, thus generating knowledge earlier than with conventional methods. Given current concerns about neonatal research, the lack of adequate licensing of drugs used in the neonate, and the need to evaluate emergency treatments, such as neuroprotection in asphyxiated neonates,[25] this debate must take place urgently.

D J Manning MD, MSc, FCPCH, DCH, DRCOG, is a Consultant Paediatrician in the Department of Paediatrics, Wirral Hospital, Wirral, Merseyside CH49 5PE.

References

1 Conroy S, McIntyre J, Choonara I. Unlicensed and off label drug use in neonates. *Archives of Disease in Childhood* 1999;**80**:F142-5.
2 Samuels MP, Raine J, Wright T, Alexander JA, Lockyer K, Spencer SA, *et al*. Continuous negative extrathoracic pressure in neonatal respiratory failure. *Pediatrics* 1996;**98**:1154-60.
3 Rothman DJ. Ethics and human experimentation. Henry Beecher revisited. *New England Journal of Medicine* 1987;**317**: 1195-9.
4 Perlman NB, Freedman JL, Abramovitch R, Whyte H, Kirpalani H, Perlman M. Informational needs of parents of sick neonates. *Pediatrics* 1991; 88:512-8.
5 Allmark P. Should Zelen pre-randomised consent designs be used in some neonatal trials? *Journal of Medical Ethics* 1999;**25**: 325-9.
6 Snowdon C, Garcia J, Elbourne D. Making sense of randomisation; responses of parents of critically ill babies to random allocation of treatment in a clinical trial. *Social Science and Medicine* 1997;**45**:1337-55.
7 Mason S. Obtaining informed consent for neonatal randomised controlled trials - an elaborate ritual? *Archives of Disease in Childhood* 1997;**76**:F143-5.
8 Harth SC, Thong YH. Parental perceptions and attitudes about informed consent in clinical research involving children. *Social Science and Medicine* 1995;**40**:1573-7.
9 van Stuijvenberg M, Suur MH, de Vos S, Tjiang GCH, Steyerberg EW, Derksen-Lubsen G, *et al*. Informed consent, parental awareness, and reasons for participating in a randomised controlled trial. *Archives of Disease in Childhood* 1998;**79**:120-5.
10 Hewlett S. Consent to clinical research - adequately voluntary or substantially influenced? *Journal of Medical Ethics* 1996;**22**: 232-7.
11 Harth SC, Thong YH. Sociodemographic and motivational characteristics of parents who volunteer their children for clinical research: a controlled study. *British Medical Journal* 1990; **300**:1372-5.
12 Silverman WA. The myth of informed consent: in daily clinical practice and in clinical trials. *Journal of Medical Ethics* 1989;**15**: 6-11.
13 Walterspiel JN. Informed consent: influence on patient selection among critically ill premature infants. *Pediatrics* 1990; **85**:119-21.
14 Informed consent in emergency research. Consensus statement from the Coalition Conference of Acute Resuscitation and Critical Care Researchers. *Journal of the American Medical Association* 1995;**273**:1283-7.
15 Adams JG, Wegener J. Acting without asking: an ethical analysis of the Food and Drug Administration waiver of informed consent for emergency research. Annals of Emergency Medicine 1999;**33**:218-23.
16 Morley C. Consent is not always practical in emergency treatments. *British Medical Journal* 1997;**314**:1480.
17 Modi N. Clinical trials and neonatal intensive care. *Archives of Disease in Childhood* 1994;**70**:F231-2.
18 Zupancic JA, Gillie P, Streiner DL, Watts JL, Schmidt B. Determinants of parental authorization for involvement of newborn infants in clinical trials. *Pediatrics* 1997; **99,1**:117. URL: http://www.pediatrics.org/ggi/content/full/99/1/e6
19 Mutch L, King R. Obtaining parental consent - opting in or opting out? *Archives of Disease in Childhood* 1985;**60**:979-80.
20 Rogers CG, Tyson JE, Kennedy KA, Broyles S, Hickman JF. Conventional consent with opting in versus simplified consent with opting out: an exploratory trial for studies that do not increase patient risk. *Journal of Pediatrics* 1998;**132**:606-11.
21 Kennedy I, Sells RA, Daar AS, Guttmann RD, Hoffenberg R, Lock M, *et al*. The case for "presumed consent" in organ donation. *Lancet* 1998;**351**:1650-2.
22 Lantos JD. The "inclusion benefit" in clinical trials. *Journal of Pediatrics* 1999;**134**:130-1.
23 Schmidt B, Gillie P, Caco C, Roberts J, Roberts R. Do sick newborn infants benefit from participation in a randomized clinical trial? *Journal of Pediatrics* 1999;**134**:151-5.
24 Kremers MS, Whisnant DR, Lowder L, Gregg L. Initial experience using the Food and Drug Administration guidelines for emergency research without consent. *Annals of Emergency Medicine* 1999;**33**:224-9.
25 Edwards AD, Azzopardi D. Hypothermic neural rescue treatment: from laboratory to cotside? *Archives of Disease in Childhood* 1998;**78**:F88-91.

News and notes

The Annual Intensive Course on Medical Ethics

The Annual Intensive Course on Medical Ethics will be held from 11 - 15 September, 2000 at the Wolfson Conference Centre, Imperial College Hammersmith Hospital Campus, London.

The course provides a stimulating multidisciplinary introduction to philosophical medical ethics for medical and nursing teachers, medical practitioners, members of ethics committees and administrators. It is organised in collaboration with the Institute of Medical Ethics. Lectures/seminars, and small and large groups are led by leading international authorities in the field of medical ethics. PGEA and CME accreditation sought for 2000. (All previous courses have received full-range 10 session PGEA accreditation and 25 CME credits).

For further details, please contact: Bang Nong on Tel:+44 (0)20 7594 6882 or Hersha Mistry on Tel:+44 (0)20 7594 6884, Centre for Continuing Education, Imperial College, Room 526 Sherfield Building, London SW7 2AZ. Fax: +44 (0)20 7594 6883; Email: cpd@ic.ac.uk; http://www.ad.ic.ac.uk/cpd/medeth.htm